

## Environmental Protection Agency

## § 158.3

### Subpart V— Microbial Pesticides

- 158.2100 Microbial pesticides definition and applicability.
- 158.2110 Microbial pesticides data requirements.
- 158.2120 Microbial pesticides product analysis data requirements table.
- 158.2130 Microbial pesticides residue data requirements table.
- 158.2140 Microbial pesticides toxicology data requirements table.
- 158.2150 Microbial pesticides nontarget organisms and environmental fate data requirements table.
- 158.2160 Microbial pesticides product performance data requirements.
- 158.2170 Experimental use permit data requirements—microbial pesticides.
- 158.2171 Experimental use permit microbial pesticides product analysis data requirements table.
- 158.2172 Experimental use permit microbial pesticides residue data requirements table.
- 158.2173 Experimental use permit microbial pesticides toxicology data requirements table.
- 158.2174 Experimental use permit microbial pesticides nontarget organisms and environmental fate data requirements table.

### Subpart W—Antimicrobial Pesticide Data Requirements

- 158.2200 Applicability.
- 158.2201 Antimicrobial use patterns.
- 158.2203 Definitions.
- 158.2204 Public health and nonpublic health claims.
- 158.2210 Product chemistry.
- 158.2220 Product performance.
- 158.2230 Toxicology.
- 158.2240 Nontarget organisms.
- 158.2250 Nontarget plant protection.
- 158.2260 Applicator exposure.
- 158.2270 Post-application exposure.
- 158.2280 Environmental fate.
- 158.2290 Residue chemistry.

### Subpart X–Z [Reserved]

- 158.2300–158.2500 [Reserved]

AUTHORITY: 7 U.S.C. 136–136y; 21 U.S.C. 346a.

SOURCE: 72 FR 60957, Oct. 26, 2007, unless otherwise noted.

### Subpart A—General Provisions

#### § 158.1 Purpose and scope.

(a) *Purpose.* The purpose of this part is to specify the kinds of data and information EPA requires in order to make regulatory judgments under

FIFRA secs. 3, 4, and 5 about the risks and benefits of pesticide products. Further, this part specifies the data and information needed to determine the safety of pesticide chemical residues under FFDCA sec. 408.

(b) *Scope.* (1) This part describes the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; support the reregistration of a pesticide product; support the maintenance of a pesticide registration by means of the data call-in process, e.g., as used in the registration review program; or establish or maintain a tolerance or exemption from the requirements of a tolerance for a pesticide chemical residue.

(2) This part establishes general policies and procedures associated with the submission of data in support of a pesticide regulatory action.

(3) This part does not include study protocols, methodology, or standards for conducting or reporting test results; nor does this part describe how the Agency uses or evaluates the data and information in its risk assessment and risk management decisions, or the regulatory determinations that may be based upon the data.

(c) *Scope of individual subparts.* (1) *Conventional pesticides.* Subparts A, B, C, D, F, G, K, L, N, and O apply to conventional pesticides.

(2) *Biochemical pesticides.* Subparts A, B and U apply to biochemical pesticides.

(3) *Microbial pesticides.* Subparts A, B and V apply to microbial pesticides.

(4) *Antimicrobial pesticides.* Subparts A, B, C, D, and W of this part apply to antimicrobial pesticides.

[72 FR 60957, Oct. 26, 2007, as amended at 78 FR 26978, May 8, 2013]

#### § 158.3 Definitions.

All terms defined in sec. 2 of the Federal Insecticide, Fungicide, and Rodenticide Act apply to this part and are used with the meaning given in the Act. Applicable terms from the Federal Food, Drug, and Cosmetic Act also apply to this part. Individual subparts may contain definitions that pertain solely to that subpart. The following additional terms apply to this part: